



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2001

Mr. J. Edward Carchidi
President
Ace Surgical Supply Company
1034 Pearl Street
P.O. Box 1710
Brockton, Massachusetts 02403

Re: K002075
Trade Name: Ace SDS 3.75 micrograms Screw Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: June 30, 2000
Received: July 10, 2000

Dear Mr. Carchidi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

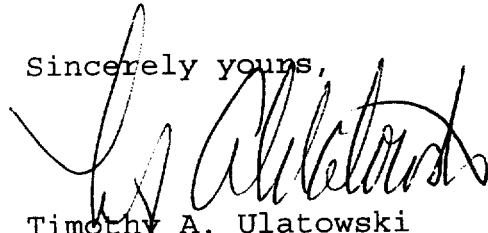
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. "A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 002 075

Device Name: ACE SDS 3.75mm Screw Dental Implants

Indications For Use:

Indications:

The ACE Surgical SDS Dental Implant Fixture is designed for use in totally or partially edentulous mandibles or maxillae to restore dentition with a fixed or removable restoration. The ACE Surgical SDS Dental Implant is designed with a 0.7mm external hexagon connection that fits with the presently marketed external hexagon prosthetic components available through ACE Surgical. This modified implant design is indicated for use to restore missing dentition in the same manner as the existing ACE Surgical Screw-Type dental implant has.

Contraindications:

The ACE Surgical SDS Dental Implant Fixture is contraindicated in patients with insufficient available bone, poor bone quality, and generalized diseases, allergies or habits (uncontrolled diabetes, blood dyscrasias, hyperthyroidism, AIDS, alcohol addiction, psychiatric disorders, oral infections, malignancies, myocardial infarctions within the last 12 months, heavy smoking, use of chewing tobacco, poor oral hygiene, etc.) that may contribute to poor healing or osteogenesis formation of bone. In addition, periodontal disease, abnormal bone conditions, severe bruxism and a cross-bite situation must be evaluated and corrected before the use of this product. The patient's good medical health status and history is also mandatory. Panoramic and periapical radiographs as well as a thorough oral inspection and palpation are also recommended to determine anatomic landmarks, dental pathology and adequacy of bone. Finally, the ACE Surgical SDS Dental Implant Fixtures are contraindicated for practitioners that are not trained in the techniques of oral implantology and trained in ACE Surgical's defined surgical protocol.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rimmer

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

File Number

K002075

Prescription Use ☒

(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐